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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,580	10/03/2000	Daniel A. Japuntich	48317USA7K.030	7366

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EXAMINER	
LEWIS, AARON J	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)
	09/678,580	JAPUNTICH ET AL.
	Examiner	Art Unit
	AARON J. LEWIS	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 16 June 2006.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 34-58 and 60-87 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 34-58 and 60-87 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 68,34-36,50-56,58,60-75,76-82, are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. ('516) in view of Soderberg (EP 0 252 890) and Shindel ('277).

As to claim 68, Simpson et al. disclose a filtering face mask that comprises: a mask body (1,2) that is adapted to fit over the nose and mouth of a wearer (fig.1); and an exhalation valve (fig.2) that is attached to the mask body, the exhalation valve comprising: a valve seat that comprises: a seal surface; an orifice (16) that is circumscribed by the seal surface; and a flap-retaining surface (portion abutting retainer 17); and a single flap (15) that has a stationary portion and only one free portion and a peripheral edge (i.e. the edge of the valve flap 15 as illustrated in fig.2 of Simpson et al. is readable upon the recited peripheral edge) that extends 360 degrees about the flap and that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free segment also being located below the stationary segment when the

filtering face mask is worn on a person and viewed from the front (i.e. fig.1 of Simpson et al. illustrates the face mask angled downwardly when donned; consequently, the free portion of valve flap 15 would be positioned below the stationary segment). (page 2, lines 37-50). The flexible flap of Simpson et al. is positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith when fluid is not passing through the orifice (page 2, lines 41-50). To the extent, if any, that the flap of Simpson et al. may not be pressed towards the seal surface in an abutting relationship therewith when fluid is not passing through the orifice resort is had to Soderberg (page 4, lines 17-23), in a face mask having an exhalation valve that is pressed towards the valve seal surface in an abutting relationship therewith, when fluid is not passing through the orifice for the purpose of ensuring and maintaining a seal between the exhalation valve and the valve seat.

It would have been obvious to modify the exhalation valve of Simpson et al. to be pressed towards the valve seat in an abutting relationship therewith when fluid is not passing through the orifice because it would have ensured and maintained a seal between the valve flap and seat as taught by Soderberg.

The difference between Simpson et al. and claim 68 is a valve cover that is disposed over the valve seat and that comprises a surface that holds the flexible flap against the flap-retaining surface in a location and position relative to the seal surface such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve, the point where

the flexible flap is mechanically held against the flap retaining surface being located off center relative to the flap.

Shindel (col.2, lines 59-66) teaches a valve securing device in the form of a valve cover (7) that is disposed over the valve seat and that comprises a surface (14) that mechanically holds flexible flap (6) against the flap retaining surface (5) in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve, the point where the flexible flap is mechanically held against the flap retaining surface being located off center (fig.2) relative to the flap. Shindel cites the advantages of simplicity of arrangement and ready removability of the cover when desired which would allow for replacement and/or cleaning of the valve and orifices.

It would have been obvious to modify the manner of attachment of the exhalation valve of Simpson et al. as modified by Soderberg to employ a cover over the valve seat because it would have provided a simple arrangement with ready removability of the cover when desired and because it would have provided protection for the exhalation valve as taught by Shindel and because Simpson et al. as modified by Soderberg teach the valve flap may be mounted to the valve seat in a variety of well known ways including clamping (page 5, line 30-page 6, line 3 of Soderberg).

As to claims 34 and 35, the particular material from which the valve seat of Simpson et al. is made and the manner of making the valve seat can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular material including plastic material. It is noted that Simpson et al. (page 2, line 39) discloses the valve flap being made from a plastic material. Consequently, it is

submitted that it would have been obvious to make the valve seat from any well known material (e.g. plastic) having known physical characteristics to achieve an expected result (i.e. physical cooperation of like plastic materials).

As to claim 36, the seal (fig.2) of Simpson et al. is illustrated as being substantially uniform and since the flexible flap (15) of Simpson et al. is disclosed as being made from plastic and since known physical characteristics of plastics include flexibility and resiliency, it would have been obvious that the flap (15) of Simpson et al. being made from plastic is "...capable of allowing the flap to display bias towards the seal surface.".

As to claim 50, while Simpson et al. is silent as to the relative surface areas of the fixed and free portions of flap (15), it is submitted that the particular relative amounts of the fixed and free portions can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular relative amounts.

As to claim 51, the flange against which the flap is secured in Simpson et al. (fig.2) is illustrated as being the same 360 degrees around the valve seat.

As to claim 52, given the downward orientation of the mask body (1,2) of Simpson et al. (fig.1) and given that any exhaled air must pass outward between the valve flap (15) and the body of the mask, it stands to reason that exhaled air will follow a path which is generally parallel to the upper surface of the body of the mask which itself is downwardly oriented as illustrated in fig.1. Therefore, exhaled air is deflected downwardly during use of the mask of Simpson et al..

As to claim 53, the mask body of Simpson et al. is cup shaped and includes at least one shaping layer and a filtration layer (page 1, lines 108-123). Simpson et al. (page 1, line 116) disclose that the shaping layer may be located on one or both sides of the filtration layer. One or both sides would include being located outside of the filtration layer.

As to claims 54-56, while Simpson et al. do not address the particular volume of a wearer's exhalation exiting the exhalation valve (12), it is submitted that since the exhalation valve (12) is expressly disclosed as opening in response to a wearer's exhalation, it would have been obvious that the valve would remain opened as long as a wearer is exhaling which would enable most if not all of the volume including 60-73% of gas exhaled by a wearer to pass through valve (12) of Simpson et al..

As to claim 58, since the mask body (1,2) of Simpson et al. is angled downwardly when positioned on a wearer's face, the valve (fig.2) mounted in cantilever fashion on mask body (1,2) of Simpson et al. is positioned substantially opposite a wearer's mouth (fig.1).

As to claim 60, the orifice (16) of Simpson et al. does not wholly correspond to the shape of the seal surface inasmuch as the boundaries of the orifice are set at a distance within the seal surface.

As to claim 61, the valve cover of Shindel has an opening (13) that is disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation.

As to claim 62, the opening (13) in the valve cover of Shindel is approximately parallel to the path traced by the second end of the flexible flap during its opening and closing.

As to claim 63, the valve cover of Simpson et al. as modified by Shindel and its opening direct exhaled fluid flow downwards when the mask is worn on a person (see fig.1 of Simpson et al.).

As to claim 64, the valve cover of Shindel includes fluid-impermeable sidewalls (11).

As to claim 65, the opening (13) in the valve cover of Shindel is at least the size of the orifice in the valve seat.

Claim 66 is substantially equivalent in scope to claim 68 and is included in Simpson et al. as modified by Soderberg and Shindel for the reasons set forth above with respect to claim 68. Soderberg (page 4, lines 20-21) teach the valve flap is pressed towards the seal surface in substantial abutting relationship therewith under any orientation of the valve when a fluid is not passing through the orifice.

As to claims 67,69, the valve cover of Shindel is secured to the valve seat by friction fit (11,15) to a wall (5,8) of the valve seat.

As to claim 70, Shindel (figs.3 and 4) illustrates the valve cover (10) having fluid impermeable sidewalls that support a fluid impermeable ceiling, and wherein the valve cover has an opening (12) that is disposed directly in the path of fluid flow, the fluid impermeable sidewalls and the ceiling and the positioning of the opening in the valve cover causing the fluid flow to be directed downwardly away from the wearer's eyes during an exhalation when the mask is worn by a person.

As to claims 71,72,75, Shindel teaches the flexible flap being mechanically clamped between the surface on the valve cover and the flap retaining surface col.2, lines 51-55 and the flap retaining surface is not disposed in the path of the exhale flow stream and outside the region defined by the plurality of openings (#16 of Simpson et al.).

As to claim 73, Simpson et al. teach a plurality of openings (16) disposed within the orifice beneath where the flexible flap (15) is mounted to the valve seat when viewing the filtering face mask from the front in an upright position.

As to claim 74, Simpson et al. (fig.2) as modified by Shindel provide an exhalation valve that opens responsive to a wearer's exhalation (page 2, lines 37-42). Accordingly, the exhalation valve constitutes a structure that is fully capable of performing the recited function of being a primary passage for a wearer's exhaled air.

As to claims 76-77, the flap retaining surface of Simpson et al. (fig.2) and Shindel (fig.2) illustrate the flap retaining surface to be spaced at some undisclosed distance from the nearest orifice portion. The particular distance constitutes a results effective variable and as such can be arrived at through mere routine obvious experimentation and observation. For example, a mask for children may have a smaller distance between the flap retaining surface and nearest portion of the orifice than in a mask for adults due to the elements that make up such a mask being generally smaller for children. Applicant has provided no criticality for any particular distance including 1-3.5mm; therefore, it is submitted that other distances would have performed equally well including the distances illustrated in Simpson et al. and Shindel.

As to claim 78, each of Simpson et al.(fig.2), Soderberg (figs.2-3) and Shindel (fig.2) illustrates the peripheral edge of the free end of the valve flap corresponding to the shape of the seal surface where the free portion makes contact therewith.

As to claims 79-82, the function of the valve flap in Simpson et al. as modified by Soderberg and Shindel remains the same regardless of the dimensions of the valve flap; therefore, the particular dimensions of the valve flap in Simpson et al. as modified by Soderberg and Shindel constitute optimizable results effective variables and as such can be arrived at through mere routine obvious experimentation and observation. Applicants have provided no criticality for the dimensions of the valve flap and as such the size of the valve flap in Simpson et al. as modified by Soderberg and Shindel would have performed equally well.

3. Claims 37-49,83-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. ('516) in view of Soderberg (EP 0 252 890) and Shindel ('277) as applied to claims 68,34-36,50-56,58,60-75 above, and further in view of Cover ('183).

The difference between Simpson et al. as modified by Soderberg and Shindel and claim 37 is the flexible flap having a curved profile when viewed from a side elevation.

Cover (page 2, col.1, lines 3-6, lines 15-17, lines 22-33, lines 48-51) teaches an exhalation valve flap (23) when secured to the valve seat (17) at its fixed portion has a curved profile when viewed from a side elevation (figs.1,2,4) for the purpose of improving the closing action of the valve flap, improving the retention of the valve flap in effective registration with the apertures of the valve seat and causing the valve flap to function more efficiently.

It would have been obvious to modify the shape of the valve seat of Simpson et al. to have a curved profile when viewed from a side elevation because it would have improved the closing action of the valve flap, improved the retention of the valve flap in effective registration with the apertures of the valve seat and caused the valve flap to function more efficiently as taught by Cover.

As to claims 38-39, the flap (15) of Simpson et al. is disclosed as being made from plastic and/or rubber. The physical characterisics of plastic and rubber include elasticity. Consequently, the particular material from which the valve flaps of Simpson et al. are made can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular elasticity of such a material. One of ordinary skill would recognize the need for routine experimentation and observation in an effort to arrive at a range of elasticities of such valve flaps which would be open and close responsive to a wearer's exhalation and cessation of exhalation in a manner which protects the wearer.

As to claims 40 and 41, the degree of seal between the valve flap and valve sealing surface of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular degree of seal including one meeting the standards as set forth in 30CFR 11.183-2, July 01, 1991. Further, it stands to reason that one of ordinary skill would strive to make a face mask in accordance with at least minimum current government standards of operation and including a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hrs. at 70 degrees centigrade.

As to claims 42-46,48,49, the particular dimensions, the particular material including the hardness of the material of the flexible flap (15) of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency. One of ordinary skill would have recognized that the particular dimensions and the particular material including hardness of the material would have been dependent upon the airflow requirements of a group of wearers, that is, an adult would require a mask and valve of a size and material that is capable of handling respiratory airflows typical of adults whereas a child or an adult with a compromised respiratory system would require a mask and valve of a size and material that is capable of handling lesser respiratory airflows.

As to claim 47, the one free portion of the flexible flap of Simpson et al. as further modified by Cover (figs.1-4,6) has a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface.

As to claim 83, Cover (figs.1-4,6) teaches the flexible flap being curved over the orifice.

As to claim 84, Simpson et al. (figs.1 and 2) illustrate a plurality of orifices (16) disposed beneath where the flexible flap is mounted to the valve seat when viewing the filtering face mask from the front in an upright position.

As to claim 85, Simpson et al. (figs.1 and 2) illustrate a plurality of orifices (16) through which a wearer's exhaled air passes during exhalation.

As to claim 86, Simpson et al. (fig.2) illustrate the flap retaining surface (#17) being outside the region defined by the plurality of openings (16).

As to claim 87, the flap retaining surface of Simpson et al. (fig.2) and Shindel (fig.2) illustrate the flap retaining surface to be spaced at some undisclosed distance from the nearest orifice portion. The particular distance constitutes a results effective variable and as such can be arrived at through mere routine obvious experimentation and observation. For example, a mask for children may have a smaller distance between the flap retaining surface and nearest portion of the orifice than in a mask for adults due to the elements that make up such a mask being generally smaller for children. Applicant has provided no criticality for any particular distance including 1-3.5mm; therefore, it is submitted that other distances would have performed equally well including the distances illustrated in Simpson et al. and Shindel.

Response to Arguments

4. Applicant's arguments filed 06/16/2006 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants' argument that the valve of Soderberg is held against the seat due to the material of the valve membrane is not accurate. Soderberg (page 4, lines 17-21) discloses that the beveled edge of the valve membrane contributes to its sealing against the valve seat. Soderberg (page 5, lines 10-13) discloses the manner of attachment in combination with the beveled sealing edge will guarantee absolute tightness between

the valve seat and valve member. Soderberg (page 6, lines 1-3) discloses optional methods of attachment including clamping of the valve membrane to the seat. Therefore, Soderberg makes clear that the reason for the sealing of the valve membrane to the valve seat lies in the combination of the manner of attachment (which is peripheral as disclosed at page 5, lines 22-29) and the beveled edge and not solely in the material of the valve membrane as argued by applicants.

Applicants' arguments that Shindel alone lacks disclosure of the valve flap being pressed towards the seal surface under any orientation of the valve may be accurate; however, it is the combination of Simpson as modified by Soderberg and Shindel which teach a valve flap being clamped against the valve seat via a valve cover (Shindel) under any orientation of the valve (Soderberg).

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Aaron J. Lewis
August 21, 2006